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(54) **ROTATIONAL THROMBECTOMY WIRE**

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CPC ***A61B 17/320758*** (2013.01); *A61B 2017/320733* (2013.01); *A61M 2025/09083* (2013.01)

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USPC 606/159, 180, 200; 600/585
See application file for complete search history.

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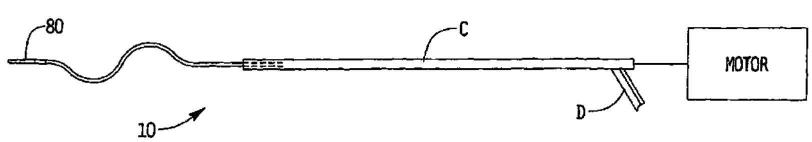
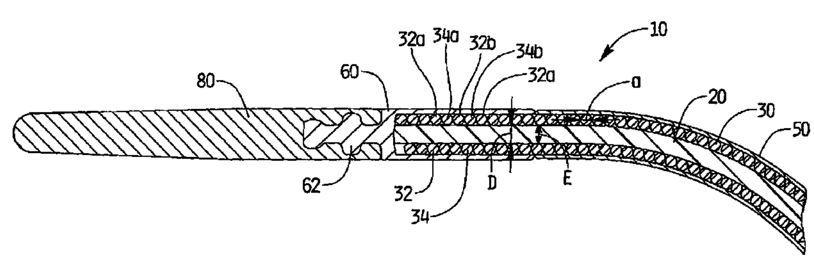
(57) **ABSTRACT**

A rotatable thrombectomy wire for breaking up thrombus or other obstructive material comprising an inner core composed of a flexible material and an outer wire surrounding at least a portion of the inner core. The outer wire has a sinuous shaped portion at a distal region. The inner core limits the compressibility of the outer wire. The outer wire is operatively connectable at a proximal end to a motor for rotating the wire to macerate thrombus.

20 Claims, 4 Drawing Sheets





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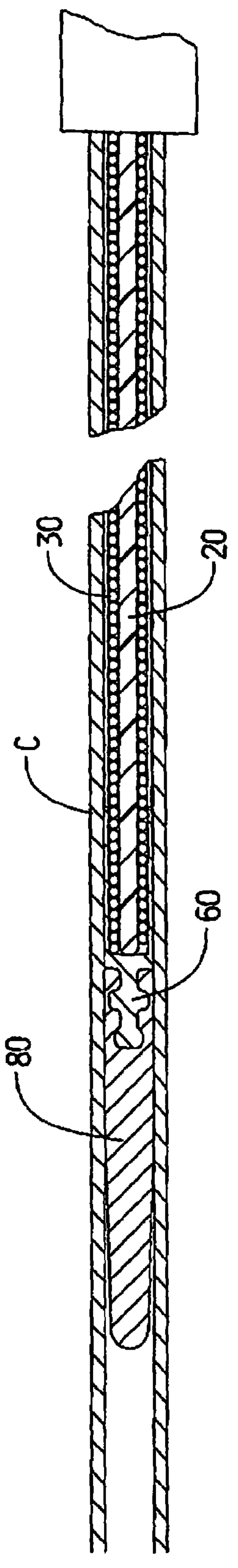

FIG_1

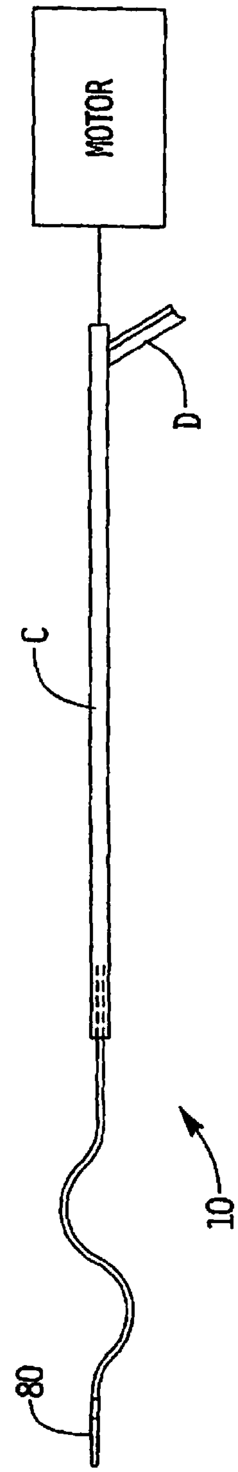

FIG_2

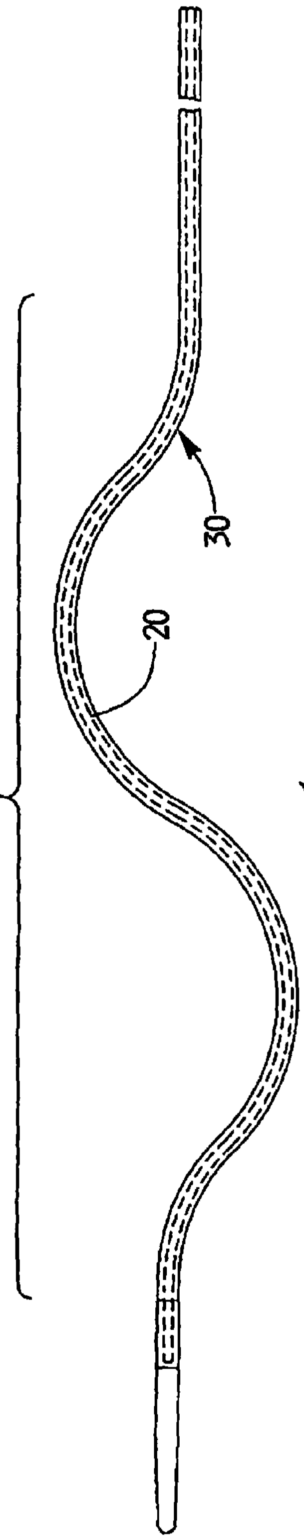

FIG. 3

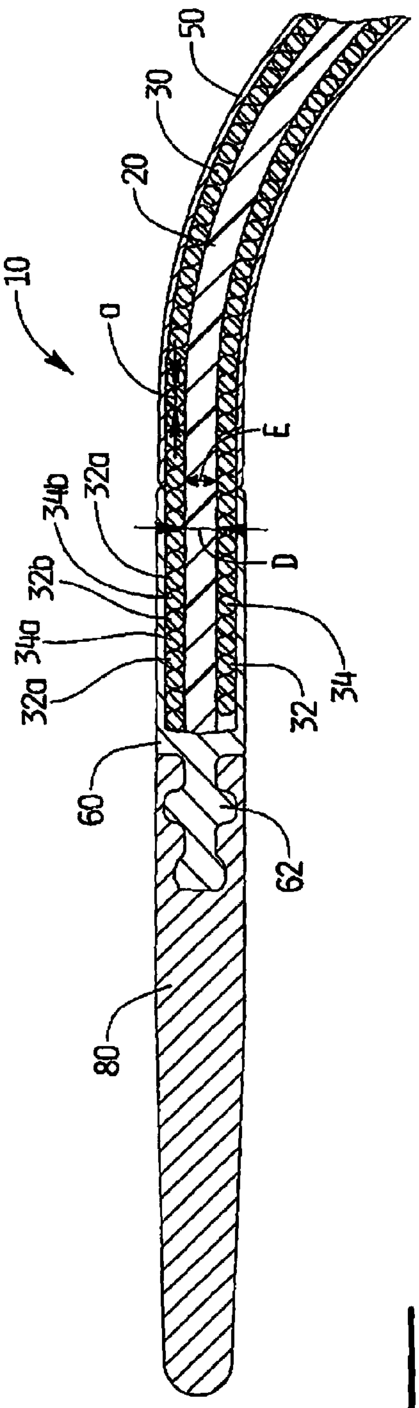

FIG. 4

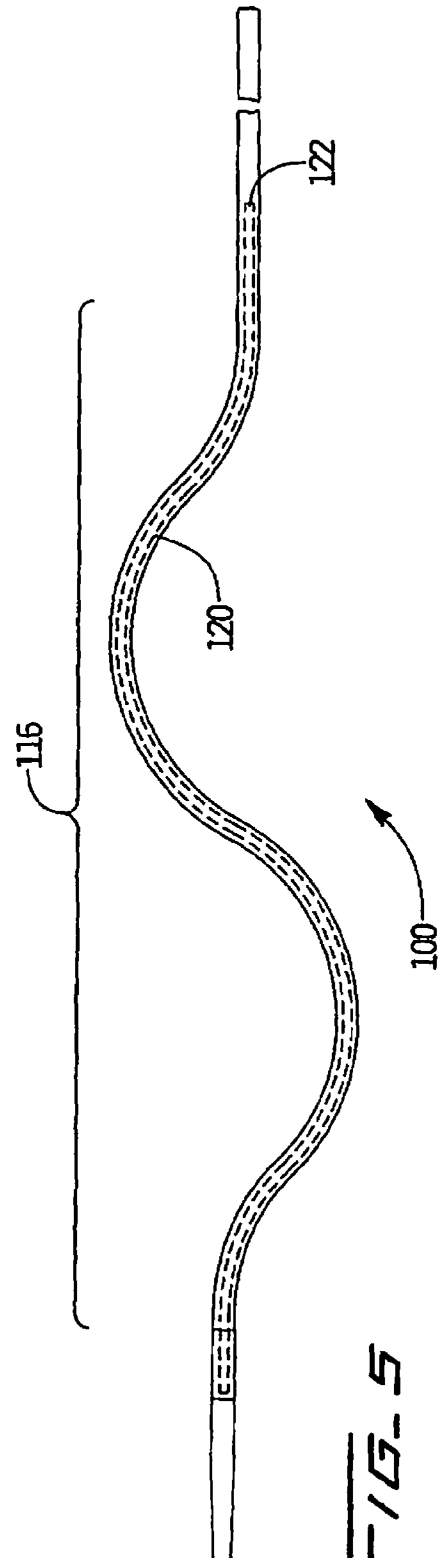

FIG. 5

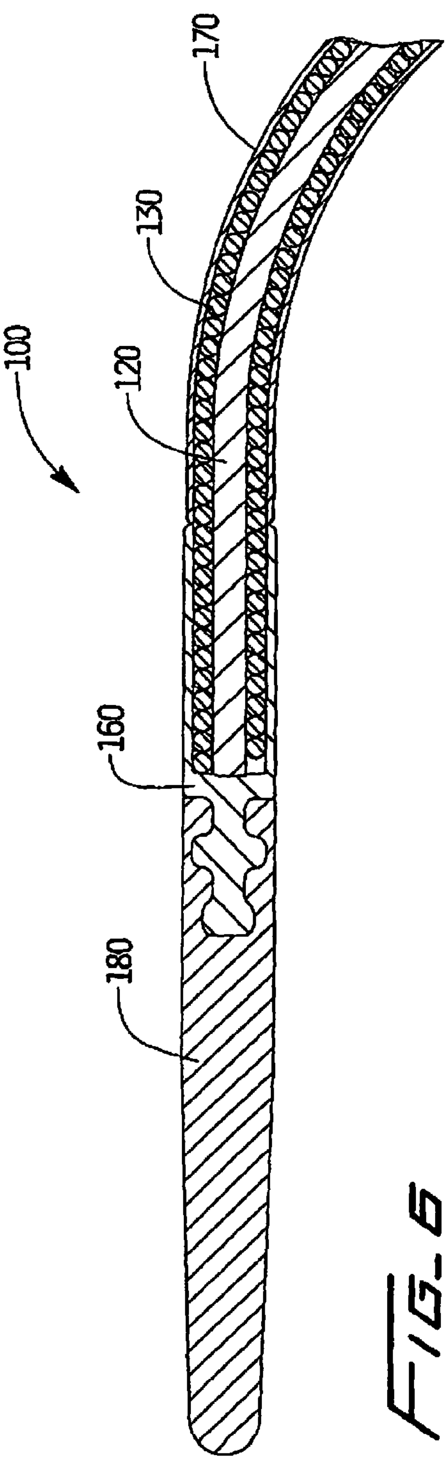

FIG. 6

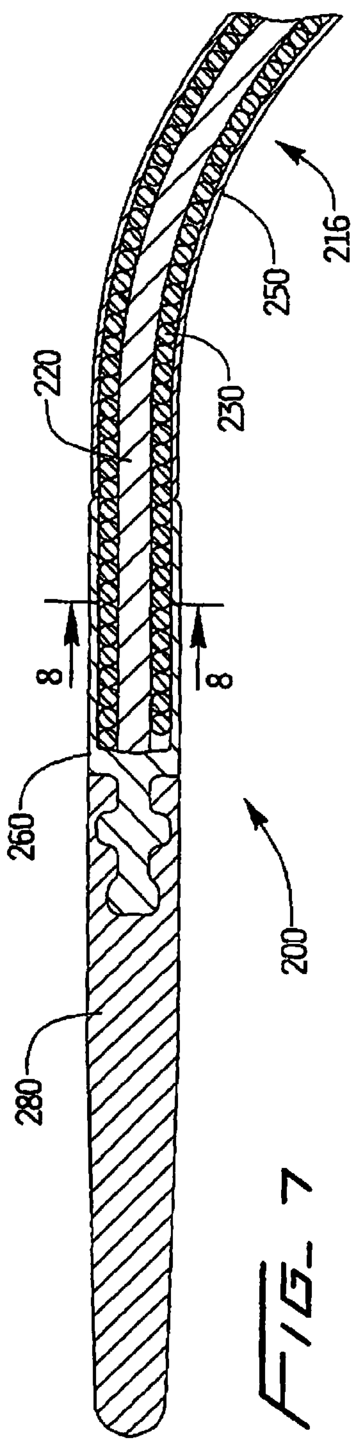

FIG. 7

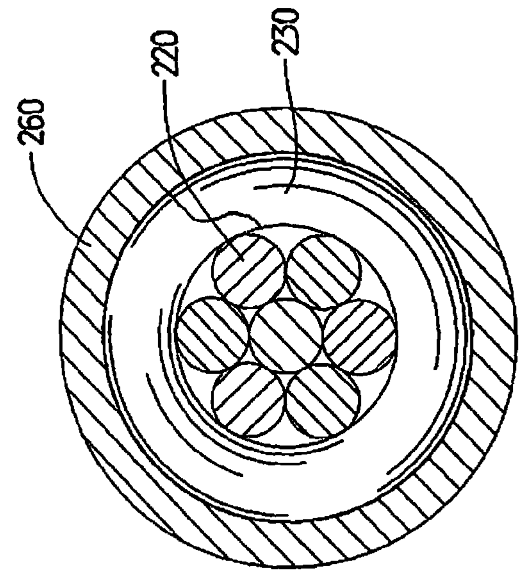

FIG. 8

ROTATIONAL THROMBECTOMY WIRE

This application is a continuation of application Ser. No. 13/276,398, filed on Oct. 19, 2011, which is a continuation of application Ser. No. 12/854,378, filed on Aug. 11, 2010, now U.S. Pat. No. 8,062,317, which is a divisional of application Ser. No. 11/017,112, filed on Dec. 20, 2004, now U.S. Pat. No. 7,819,887, which claims benefit of provisional application Ser. No. 60/628,623, filed Nov. 17, 2004. The entire contents of each of these applications are incorporated herein by reference.

BACKGROUND

1. Technical Field

This application relates to a rotational thrombectomy wire for clearing thrombus from native vessels.

2. Background of Related Art

In one method of hemodialysis, dialysis grafts, typically of PTFE, are implanted under the patient's skin, e.g. the patient's forearm, and sutured at one end to the vein for outflow and at the other end to the artery for inflow. The graft functions as a shunt creating high blood flow from the artery to the vein and enables access to the patient's blood without having to directly puncture the vein. (Repeated puncture of the vein could eventually damage the vein and cause blood clots, resulting in vein failure.) One needle is inserted into the graft to withdraw blood from the patient for transport to a dialysis machine (kidney machine); the other needle is inserted into the graft to return the filtered blood from the dialysis machine to the patient. In the dialysis machine, toxins and other waste products diffuse through a semi-permeable membrane into a dialysis fluid closely matching the chemical composition of the blood. The filtered blood, i.e. with the waste products removed, is then returned to the patient's body.

Over a period of time, thrombus or clots may form in the graft. Thrombus or clots may also form in the vessel. One approach to break up these clots and other obstructions in the graft and vessel is the injection of thrombolytic agents. The disadvantages of these agents are they are expensive, require lengthier hospital procedures and create risks of drug toxicity and bleeding complications as the clots are broken.

U.S. Pat. No. 5,766,191 provides another approach to breaking up clots and obstructions via a mechanical thrombectomy device. The patent discloses a basket having six memory wires expandable to press against the inner lumen to conform to the size and shape of the lumen. This device could be traumatic if used in the vessel, could denude endothelium, create vessel spasms and the basket and drive shaft could fracture.

U.S. Pat. No. 6,090,118 discloses a mechanical thrombectomy device for breaking up clots. The single thrombectomy wire is rotated to create a standing wave to break-up or macerate thrombus. U.S. Patent Publication No. 2002/0173812 discloses another example of a rotational thrombectomy wire for breaking up clots. The thrombectomy wire has a sinuous shape at its distal end and is contained within a sheath in a substantially straight non-deployed position. When the sheath is retracted, the distal portion of the wire is exposed to enable the wire to return to its non-linear sinuous configuration. The wire is composed of stainless steel. Actuation of the motor causes rotational movement of the wire, creating a wave pattern, to macerate thrombus. The device of the '812 patent publication is effective in atraumatically and effectively breaking up blood clots in the graft and is currently being marketed by Datascope, Inc. as the Pro-Lumen* thrombectomy catheter. In the marketed device, the wire is a bifilar wire, composed of two stainless steel wires wound side by side with a metal tip and an elastomeric tip at the distalmost end.

Although the sinuous wire of the '812 publication is effective in proper clinical use to macerate thrombus in dialysis grafts, it is not suited for use in native vessels. The device is indicated for use in grafts, and if improperly used the wire can kink or knot, and perhaps even break. The wire can also bend, making it difficult to withdraw after use, and can lose its shape. Additionally, the wire would be abrasive to the vessel and the vessel could get caught in the interstices of the wire. It could also cause vessels spasms which can cause the vessel to squeeze down on the wire which could break the wire. Similar problems would occur with the use of the device of the '118 patent in native vessels.

The need therefore exists for a rotational thrombectomy wire which can be used to clear clots or other obstructions from the native vessels. Such wire could advantageously be used not only in native vessels adjacent dialysis grafts but for deep vein thrombosis and pulmonary embolisms.

SUMMARY

The present invention advantageously provides a rotational thrombectomy wire for breaking up thrombus or other obstructive material in a lumen of a native vessel.

The present invention provides a rotational thrombectomy wire comprising an inner core composed of a flexible material and a multifilar outer wire surrounding at least a portion of the inner core. The outer wire includes at least first and second metal wires wound side by side and having a sinuous shaped portion at a distal region. The inner core at a distal portion has a sinuous shaped portion within the sinuous portion of the outer wire. The inner core limits the compressibility of the multifilar wire. The multifilar wire is operatively connectable at a proximal end to a motor for rotating the wire to macerate thrombus within the vessel.

In a preferred embodiment, the inner core is composed of nylon material. In another embodiment, the inner core is composed of shape memory material wherein the inner core assumes its sinuous shape in the memorized configuration. In another embodiment, the core comprises at least two twisted wires of stainless steel.

The thrombectomy wire preferably further includes a polymeric material surrounding at least a distal portion of the multifilar wire. In a preferred embodiment, the polymeric material comprises a shrink wrap material attached to the multifilar wire. In another embodiment, the polymeric material is a coating over the multifilar wire.

The thrombectomy wire preferably comprises a flexible and blunt tip positioned at a distal end.

The inner core can have in one embodiment an enlarged distal end to form a connection portion and a metal tip secured to a distal end of the multifilar wire has a recess to receive the enlarged end of the inner core to frictionally engage the inner core.

In one embodiment, the first and second metal wires are wound together such that the coils of the first wire occupy the space between adjacent turns of the second wire and the coils of the multifilar outer wire have an inner diameter approximately equal to an outer diameter of the inner core.

The present invention also provides a rotatable thrombectomy wire for breaking up thrombus or other obstructive material in a lumen of a vessel comprising a multifilar outer wire including at least two metal wires wound side by side and operatively connectable at a proximal end to a motor for

rotating the wire to macerate thrombus. The multifilar wire has a sinuous shaped portion at a distal region. A polymeric material surrounds at least a region of the sinuous portion of the multifilar outer wire to block the interstices of the multifilar wire.

In a preferred embodiment, the polymeric material comprises a shrink wrap material. In another embodiment, the polymeric material is a coating over the bifilar wire.

The present invention also provides a thrombectomy apparatus for breaking up thrombus or other obstructive material comprising a handle, a sheath, a battery, a motor powered by the battery, and a sinuous thrombectomy wire having at least one wire wound to form a coil and an inner core composed of a material to limit the compressibility of the coil. The coil has a sinuous portion and surrounds at least a distal region of the inner core. The inner core has a sinuous portion within the sinuous portion of the coil. The sinuous portion of the inner core and first and second wires are movable from a straighter configuration within the sheath for delivery to a sinuous configuration when exposed from the sheath.

In a preferred embodiment, a polymeric material surrounds at least a distal portion of the coil to cover the interstices of the coil. In one embodiment, the core is composed of a shape memory material wherein the memorized position of the core has a sinuous configuration. In another embodiment, the core is composed of Nylon. In another embodiment, the core is composed of at least two twisted wires of stainless steel.

The present invention also provides a method for breaking up thrombus or other obstructive material in a native vessel comprising:

providing a thrombectomy wire having an inner core composed of a flexible material and at least one outer wire surrounding at least a portion of the inner core, the outer wire has a sinuous shaped portion at a distal region and the inner core has a sinuous shaped portion within the sinuous portion of the outer wire, and a polymeric material surrounding at least a distal portion of the at least one outer wire to block the interstices of the at least one outer wire;

delivering the wire to the lumen of the native vessel such that the sinuous shaped portions of the inner core and bifilar outer wire are in a more linear configuration within a sheath;

exposing the sinuous portion of the inner core and the at least one outer wire; and

actuating a motor operatively connected to the thrombectomy wire so the sinuous portion of the at least one outer wire contacts the inner wall of the native vessel to macerate thrombus in the vessel.

BRIEF DESCRIPTION OF THE DRAWINGS

Preferred embodiment(s) of the present disclosure are described herein with reference to the drawings wherein:

FIG. **1** is a side view in partial cross-section of a first embodiment of a thrombectomy wire of the present invention shown inside a catheter sleeve for delivery;

FIG. **2** is a schematic view illustrating motorized rotation of the wire and a port for fluid delivery;

FIG. **3** is a schematic side elevational view of the sinuous portion of the thrombectomy wire to depict a first embodiment of the inner core positioned therein;

FIG. **4** is an enlarged cross-sectional view of the distalmost region of the rotational thrombectomy wire of FIG. **3**;

FIG. **5** is schematic side elevational view of the sinuous portion of the thrombectomy wire to depict a second embodiment of the inner core positioned therein; and

FIG. **6** is an enlarged side view of the distalmost region of the rotational wire of FIG. **5**;

FIG. **7** is a schematic side elevational view of the sinuous portion of the thrombectomy wire to depict a third embodiment of the inner core positioned therein; and

FIG. **8** is a cross-sectional view taken along line **8-8** of FIG. **7**.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

Referring now in detail to the drawings where like reference numerals identify similar or like components throughout the several views, FIGS. **3** and **4** illustrate a first embodiment of the thrombectomy wire of the present invention. The thrombectomy wire, designated generally by reference numeral **10**, includes a core **20**, a bifilar wire (coil) **30**, and shrink wrap **50**. The bifilar wire **30** is formed by two stainless steel wires **32**, **34**, wound together. As shown they are wound side by side so the cross-sectional area or diameter "a" of the wire fills the space between adjacent turns of the other wire. For example, turns **32***a* and **32***b* are filled by respective turns **34***a*, **34***b* as shown. Preferably the bifilar wire **30** has a length of about 30 inches and a diameter of about 0.030 inches to about 0.040 inches and more preferably about 0.035 inches. When used in deeper native vessels, e.g. deep veins of the legs or pulmonary circuit, the wire **30** can have a length of about 52 inches. Other dimensions are also contemplated.

The distal region **16** of the bifilar wire **30** is formed into a sinuous or s-shape to contact the vessel wall as the wire rotates.

Although in the preferred illustrated and described embodiments, the outer wire is a multifilar wire in the form of a bifilar wire (two wires), a different number of wires could be wound to form the outer wire component of the thrombectomy wire of the present invention. In yet another embodiment the outer wire can comprise a single wound wire.

The bifilar wire **30** is preferably cold formed into an over-formed s-shape. The bifilar wire is heated, for example at about 670 degrees Fahrenheit, which removes residual stresses and changes the shape of the "s" so it warps back to its desired shape. This stress relief process makes the wire more dimensionally stable.

A tip **80**, preferably composed of rubber, Pebax, or other elastomeric materials, is mounted at the distalmost tip of the wire **10** to provide the wire **10** with an atraumatic distal tip to prevent damage to the vessel wall during manipulation and rotation of the wire. A metal lip **60** is attached by laser welding or other methods to the distal end of the bifilar wire **30**. The metal tip **60** has an enlarged dumbbell shaped head **62** to facilitate attachment to tip **80**. The flexible tip **80** is attached by injection molding over the machined tip. Other attachment methods are also contemplated.

With continued reference to FIG. **4**, a core **20** is positioned within the bifilar wire **30** and preferably has an outer diameter E substantially equal to the inner diameter D of the coil. The core at a distal portion has a sinuous shaped portion within the sinuous shaped portion of the outer wire **30**, corresponding to and formed by the sinuous shape of outer wire **30**. In one embodiment, the core extends the entire length of the bifilar wire **30** and this is shown in the schematic drawing of FIG. **3**. The core **20** can alternatively have a length of about 4-5 inches so it extends through the distal linear portion and sinuous portion of the wire **30**. That is, in such embodiment, the core extends through the portion of the wire that is exposed from the sheath and used to macerate thrombus. It is also contemplated that the core can extend within a shorter or longer length of the bifilar wire.

The core **20** is composed of a flexible material which will limit the compressibility of the wire **30** during use. The core in the embodiment of FIG. **3** is composed of Nylon, and preferably a drawn Nylon monofilament. Other possible materials include, for example, Teflon, polypropylene, PET, and fluorocarbon. The Nylon provides a non-compressible material to limit the compressibility of the wire **30** during use. That is, as noted above, the Nylon core preferably has a diameter E to fill the inside of the coil **30**, e.g. a diameter of about 0.008 inches to about 0.013 inches, and preferably about 0.012 inches. (Other dimensions are also contemplated.) This enables the coil (bifilar wire) **30** to compress only to that diameter. By limiting compressibility it strengthens the wire as it reduces its degree of elongation if it is under torque. It also prevents bending or knotting of the wire which could otherwise occur in native vessels. It increases the torsional strength of the wire and also strengthens the wire to accommodate spasms occurring in the vessel. An enlarged distal head, such as ball tip (not shown), can be provided on the core **20** to fit in a recess of machined tip **60**. As an alternative, core **20** can be attached by adhesive at the tip, welded, crimped, soldered or can alternatively be free floating.

The shrink wrap material **50** covers a portion of the bifilar wire **30** proximal of the flexible tip **80** to block the interstices of the coil and provide a less abrasive surface. As shown in FIG. **4**, the distal end of the shrink wrap abuts the proximal end of the tip **60**. The shrink wrap can be made of PET, Teflon, Pebax, polyurethane or other polymeric materials. The material extends over the exposed portion of the wire **30** (preferably for about 3 inches to about 4 inches) and helps to prevent the native vessel from being caught in the coil and reduces vessel spasms. Alternatively, instead of shrink wrap, a coating can be applied to the coil formed by the bifilar wire to cover the interstices

FIGS. **5** and **6** illustrate an alternate embodiment of the thrombectomy wire of the present invention, designated generally by reference numeral **100**. Wire **100** is identical to wire **10** of FIG. **1**, except for the inner core **120**. It is identical in that it has a bifilar wire **130**, a shrink wrap **170**, an elastomeric tip **180** and metal, e.g. stainless steel, tip **160**.

In this embodiment, the core **120** is composed of a shape memory material, preferably Nitinol (a nickel titanium alloy), which has a memorized configuration of a sinuous or s-shape substantially corresponding to the s-shape of the bifilar wire **130**. In the softer martensitic state within the sheath, core **120** is in a substantially linear configuration. This state is used for delivering the wire to the surgical site. When the wire is exposed to warmer body temperature, the core **120** transforms to its austenitic state, assuming the s-shaped memorized configuration. Cold saline is delivered through the catheter during delivery to maintain the core **120** in this martensitic state; the warming occurs by exposure to body temperature to transform the core **120** to the memorized state. Such memorized s-shape helps maintain the s-shape of the bifilar wire **130** during use. Cold saline can also be delivered to the core **120** at the end of the procedure to facilitate withdrawal.

The Nitinol core **120**, like the Nylon core **20**, is not compressible so it will also limit the compressibility of the bifilar wire **130**. The Nitinol core **120** also will increase the stiffness of the wire **100**, thereby reducing the chance of knotting and kinking and increase the strength of the wire to accommodate any spasms in the vessel. Its shape memory helps hold the amplitude of the bifilar wire **130** during use to maintain its force against the clot for maceration upon rotation. It preferably extends about 4-5 inches so it extends through the distal linear portion and sinuous portion of the wire **130**, terminating at end **122**. Alternately it can extend a shorter or longer length within the wire **130**, or even the entire length as shown in the schematic view of FIG. **5**. It preferably has an outer diameter of about 0.008 inches to about 0.013 inches, and more preferably about 0.012 inches, corresponding to the inner diameter of the coil. Other dimensions are also contemplated.

In another embodiment, a stainless steel braid, cable, or strand of wires twisted together provides the inner core member to limit compressibility of the coil (bifilar wire) and provide increased stiffness, strength and other advantages of the core enumerated above. This is shown in the embodiment of FIGS. **7** and **8** where wire **200** has inner core **220** of seven twisted stainless steel wires. A different number of twisted wires is also contemplated. The other elements of the wire **200**, e.g., outer bifilar wire **230**, metal tip **260**, tip **280** shrink wrap **250**, etc., are the same as in wires **10** and **100** described herein.

The rotational thrombectomy wires **10**, **100** and **200** of the present invention can be used with various thrombectomy catheters to macerate thrombus within the vessel. The rotational thrombectomy wire **10** (or wire **100** or **200**) is contained within a flexible sheath or sleeve C of a catheter as shown in FIG. **1**. Relative movement of the wire and sheath C will enable the wire **10** to be exposed to assume the curved (sinuous) configuration described below to enable removal of obstructions, such as blood clots, from the lumen of the vessel.

A motor powered by a battery is contained within a housing to macerate and liquefy the thrombus into small particles within the vessel lumen. This is shown schematically in FIG. **2**. Wire **10** (or **100** or **200**) is operatively connected to the motor. Operative connection encompasses direct connection or connection via interposing components to enable rotation when the motor is actuated. The curved regions of the wire **10** or (**100** or **200**) are compressed so the wire (including the distal region **16**, **116** or **216**, respectively) is in a substantially straight or linear non-deployed configuration when in the sheath C. This covering of the wire **10** (or **100** or **200**) by sheath C facilitates insertion through an introducer sheath and manipulation within the vessel. When the flexible sheath C is retracted, the wire is exposed to enable the wire to return to its non-linear substantially sinuous configuration for rotation about its longitudinal axis within the lumen of the vessel.

Fluids, such as imaging dye can be injected through the port D into the lumen of the sheath C in the space between wire **10** (or **100** or **200**) and the inner wall of the sheath C, and exiting the distal opening to flow into the vessel. This imaging dye provides an indication that fluid flow has resumed in the vessel. The lumen of the sheath can also receive cold saline to cool the Nitinol core **120** as described above.

The rotational thrombectomy wires **10**, **100** and **200** of the present invention can also be used with the thrombectomy catheters having one or more balloons such as the balloon described in the '812 publication. The wires **10**, **100** and **200** can further be used with other thrombectomy catheters.

While the above description contains many specifics, those specifics should not be construed as limitations on the scope of the disclosure, but merely as exemplifications of preferred embodiments thereof. Those skilled in the art will envision many other possible variations that are within the scope and spirit of the disclosure as defined by the claims appended hereto.

What is claimed is:

1. A method for breaking up thrombus or other obstructive material in a native vessel comprising:

providing a thrombectomy wire having an inner core composed of a flexible material, an at least one outer wire wound over at least a portion of the inner core forming a coil with an exterior surface extending proximally of a distalmost end of the coil, wherein the coil has a sinuous shaped portion at a distal region and the inner core has a sinuous shaped portion within the sinuous shaped portion of the coil, a polymeric material positioned over the exterior surface of at least a first portion of the coil to block interstices of the at least one outer wire, a separate distal tip component, a portion of the distal tip component positioned over the exterior surface of a second portion of the coil, and a flexible elongated polymeric tip positioned over the distal tip component and extending distally therefrom, the distal tip component extending distally of the distalmost end of the coil and extending proximally of a proximalmost end of the flexible elongated polymeric tip;

delivering the thrombectomy wire to the lumen of the native vessel such that the sinuous shaped portions of the inner core and coil are in a more linear configuration within a sheath;

exposing the sinuous shaped portion of the coil so the sinuous shaped portion is in a sinuous configuration; and

actuating a motor operatively connected to the thrombectomy wire so the thrombectomy wire rotates about its longitudinal axis so the sinuous shaped portion of the coil contacts the inner wall of the native vessel to macerate thrombus in the vessel as the thrombectomy wire rotates.

2. The method of claim **1**, further comprising the step of retracting the thrombectomy wire during rotation.

3. The method of claim **1**, further comprising the step of injecting an imaging dye into the vessel.

4. The method of claim **3**, further comprising the steps of delivering the thrombectomy wire through the sheath and the step of injecting the imaging dye injects the dye through a lumen in the sheath in a space between the thrombectomy wire and an inner wall of the sheath.

5. The method of claim **1**, wherein the inner core limits the compressibility of the thrombectomy wire.

6. The method of claim **5**, wherein the inner core has an outer diameter to fill an inside of the coil so the coil only compresses to the outer diameter.

7. The method of claim **1**, wherein the step of actuating the motor causes the thrombectomy wire to contact the inner wall of the native vessel for treatment of deep vein thrombosis.

8. The method of claim **1**, wherein the step of actuating the motor causes the thrombectomy wire to contact the inner wall of the native vessel for treatment of pulmonary embolism.

9. The method of claim **1**, wherein the polymeric material is applied as a coating.

10. The method of claim **1**, wherein the polymeric material is applied as a shrink wrap material.

11. The method of claim **1**, wherein the at least one outer wire comprises a bifilar wire formed by first and second wires wound together side by side so a diameter of the first wire fills a space between adjacent turns of the second wire.

12. The method of claim **1**, wherein the inner core includes multiple wires twisted together.

13. The method of claim **1**, wherein the inner core is attached to the distal tip component within a recess of the distal tip component.

14. The method of claim **13**, wherein the coil is attached to the distal tip component within the recess of the distal tip component.

15. The method of claim **14**, wherein the distal tip component has recessed portions along its length to receive the polymeric tip thereover.

16. The method of claim **13**, wherein the distal tip component is a metal tip and extends distally of a distal end of the inner core.

17. The method of claim **16**, wherein the distal tip component extends proximally of the distal end of the inner core.

18. The method of claim **17**, wherein the polymeric material extends proximally of the distal tip component.

19. The method of claim **1**, wherein the polymeric tip is axially spaced from the distalmost end of the outer wire.

20. The method of claim **1**, wherein the polymeric tip has a solid region extending along a longitudinal axis thereof.

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